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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,579	12/27/2000	Alan Ebringer	092620269448	1579
75	590 09/10/2003	•		
Joseph T Leone Intellectual Property Department Dewutt Ross & Stevens SC			EXAMINER	
			SWARTZ, RODNEY P	
800 Excelsior Drive Suit 401 Madison, WI 53717-1914			ART UNIT	PAPER NUMBER
<b>,</b>			1645	$\cap$
			DATE MAILED: 09/10/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

### Applicant(s) Application No. EBRINGER, ALAN 09/646,579 **Advisory Action** Art Unit Examiner 1645 Rodney P. Swartz, Ph.D. -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 31July2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. PERIOD FOR REPLY [check either a) or b)] a) $\square$ The period for reply expires $\underline{3}$ months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 1. A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal. 2. The proposed amendment(s) will not be entered because: (a) they raise new issues that would require further consideration and/or search (see NOTE below); (b) they raise the issue of new matter (see Note below); Frank pr (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) they present additional claims without canceling a corresponding number of finally rejected claims. NOTE: . 3. Applicant's reply has overcome the following rejection(s): They have all 4. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Detailed Action. 6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection. 100 7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. W. at 1 The status of the claim(s) is (or will be) as follows: Claim(s) allowed: 1-3,5-8 and 17. Claim(s) objected to: \_\_\_\_\_. a diameter Claim(s) rejected: 4,9-16,18. Claim(s) withdrawn from consideration: . . 8. The proposed drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.

U.S. Patent and Trademark Office PTOL-303 (Rev. 04-01)

10. Other: \_\_\_

J. Mary Brand

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9. Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). \_\_\_\_\_.

Application/Control Number: 09/646,579

Art Unit: 1645

#### **DETAILED ACTION**

- 1. Applicant's Response to Final Office Action, received 31July2003, paper#21, is acknowledged. The signed and dated rule 132 Declaration of Alan Ebringer, is acknowledged.
- 2. Claims 1-18 are pending and under consideration.

## **Rejection Maintained**

3. The rejection of claims 4, 9-16, and 18 under 35 U.S.C. 112, first paragraph, scope of enablement for purified/isolated individual antigens of *Acinetobacter calcoaceticus*, or for diagnosis of other demyelinating diseases, is maintained for reasons of record.

Applicant argues that because bovine spongiform encephalopathy is transmissible to other species it is extremely reasonable to conclude that a test that diagnoses spongiform encephalopathy in bovines will also reveal speongiform encephalopathy in other mammals too.

The examiner has considered applicant's argument and finds it persuasive in view of the prior amendments of the claims which restricted the scope of the claims to methods of detecting multiple sclerosis, Creutzfeld-Jakob disease and spongiform encephalopathy in mammals.

Applicant argues that the Declaration of Dr. Ebringer clearly indicates that the claimed methods function not only with whole *Acinetobacter* species, but an isolated antigen derived from *Acinetobacter*, i.e., QNFISRFAWGEVNSR.

The examiner has considered applicant's arguments and Dr. Ebringer's Declaration, but does not find them persuasive. The instant specification provides guidance and examples of only whole *Acinetobacter calcoaceticus*. The Declaration does not utilize the amino sequence of

Application/Control Number: 09/646,579

Art Unit: 1645

the instant specification, but uses only a single antigen which consists of an amino acid sequence which differs from the SEQ ID NO:2 of the instant specification. The instant specification teaches a 9-mer sequence, ISRFAWGEV, while the Declaration teaches a 15-mer sequence, QNFISRFAWGEVNSR. There is no evidence to distinguish whether the binding of antibodies is only due to binding to the sequence ISRFAWGEV, which is taught in the specification, or due to binding requiring the amino acids added onto the base sequence, i.e., QNF and NSR. There is no way to determine if the addition of the amino acids may result in a new epitope at each end of the polypeptide, a new epitope due to new folding, or no change. Therefore, because the Declaration does not utilize the sequence as taught in the specification, and additionally utilizes only one sequence, the examiner does not find the evidence persuasive for the scope of the instant claims, i.e, any/all single antigen present in, derived from, or prepared sequence corresponding to *Acinetobacter* species.

### Conclusion

1. Claims 4, 9-16, and 18 remain rejected. Claims 1-3, 5-8, and 17 are free of prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

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Application/Control Number: 09/646,579

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

PRIMARY EXAMINER

Art Unit 1645

September 10, 2003